Appendix 1. PRE-ACT BASELINE ASSESSMENT (What Participant Saw/*Scale Name)* Original or Adapted scales in full, or references for previously published scales

No legend

Appendix 2. PRE-ACT Post-Intervention Assessment

The Post-Intervention Assessment consisted of the baseline assessment (without Demographics), plus the following scales asking them about their satisfaction with the intervention, as well as for feedback on the program.

Appendix 3. PRE-ACT Post-Consultation Assessment

No legend

Appendix 4. List of Video Library Titles

No legend

Appendix 5. Control Condition Adapted from NCI Text

No legend

Appendix 6. Appendix 6: Appendix 6: Comparisons of demographic characteristics of patients who dropped out vs. completed visits, and effects of dropout on balance in baseline characteristics, PRE-ACT vs. Control

No legend

Appendix 7. Impact of Videos on Change in Knowledge Score
For subjects in the PRE-ACT arm who did not have a correct response to each knowledge item at baseline, the proportions answering the item correctly on the post-test were compared between those who watched the associated video vs. those who did not watch the assigned video. Positive differences in proportions indicate that those who watched the video had better scores for the item on the post-test compared to those who did not watch the video.

Appendix 8. Impact of Videos on Change in Attitudinal Barrier Scores
For subjects in the PRE-ACT arm who answered 3=”Neither Agree nor Disagree “, 4=”Somewhat Agree “, or 5=”Strongly Agree“ to each attitudinal barrier item were divided into those who watched vs. did not watch the assigned video addressing that particular barrier, and the difference in mean post-test scores between those not watching vs. watching the video are summarized (mean and 95% CI). Mean differences that are positive indicate that those watching the video had more favorable post-test scores compared to those who did not watch the video.

Appendix 1: PRE-ACT BASELINE ASSESSMENT (What Participant Saw/*Scale Name)* Original or Adapted scales in full, or references for previously published scales

Your Background/*Demographics*

Directions: Please provide the following information about yourself. To answer the questions, click on the circle or box next to the answer you want to choose.

1. What is your gender?
- ❍ **Male**
- ❍ **Female**

2. What is your current marital/partnered status?
- ❍ **Married**
- ❍ **Divorced**
- ❍ **Widowed**
- ❍ **Separated**
- ❍ **Never been married**
- ❍ **A member of an unmarried couple**

3. Do you live with others? ❍ **Yes** ❍ **No**

3a. If you live with others, who lives with you? (You may select more than one)
- ❍ **Spouse or partner**
- ❍ **Children**
- ❍ **Roommates**
- ❍ **Paid home health aide/nurse**
- ❍ **Other family members**
- ❍ **Pets**
- ❍ **Other, (please specify):**

4. What is the highest grade or level of schooling you have completed?
- ❍ **8th grade or less**
- ❍ **Some high school**
- ❍ **High school graduate**
- ❍ **Some college or technical school**
- ❍ **College graduate**

5. Are you Hispanic or Latino?
- ❍ **Yes**
- ❍ **No**

6. Which one or more of the following would you say is your race? (Please click in all boxes that apply.)
- ❍ **American Indian or Alaska Native**
- ❍ **Asian**

❍ **Black or African American**
❍ **Native Hawaiian or other Pacific Islander**
❍ **White**
❍ **Other (please specify):**

7. What is your current employment status?

❍ **Employed for wages**
❍ **Self-Employed**
❍ **Out of work for more than one year**
❍ **Out of work for less than one year**
❍ **Homemaker**
❍ **Student**
❍ **Retired**
❍ **Unable to work**

8. How much of a burden on you is the cost of your medical care?

❍ **Not a burden**
❍ **Minor burden**
❍ **Moderate burden**
❍ **Major burden**
❍ **Extreme burden**

9. Have you ever taken part in a clinical trial to treat cancer or any other disease?

❍ **Yes**
❍ **No**

Your Opinions/*Preparedness(45)* *

Directions: **Please indicate how prepared you feel for your visit with your doctor by clicking the box under the appropriate phrase to show the extent to which you agree with each statement.**

	Not at all	Very little	Somewhat	Quite a bit	A great deal
To what extent do you feel that:					
1. You recognize that taking part in a clinical trial is a decision that needs to be made?	❍	❍	❍	❍	❍
2. You are prepared to make a decision about taking part in a clinical trial?	❍	❍	❍	❍	❍
3. You know the pros and cons of your treatment options?	❍	❍	❍	❍	❍
4. You know about which pros and cons are most important?	❍	❍	❍	❍	❍
5. You know that your decision depends on what matters most to you?	❍	❍	❍	❍	❍
6. You can organize your own thoughts about the decision?	❍	❍	❍	❍	❍
7. You know how involved you want to be in this decision?	❍	❍	❍	❍	❍
8. You can identify questions you want to ask your doctor?	❍	❍	❍	❍	❍
9. You are prepared to talk to your doctor about what matters most to you?	❍	❍	❍	❍	❍
10. You are prepared for your visit with your doctor?	❍	❍	❍	❍	❍

The scoring of this scale was to calculate the mean of the items -1 multiplied by 25, resulting in a scaled score of 1-100, where a higher score reflects higher preparedness.

*adapted from Graham ID & O'Connor AM. User Manual – Preparation for Decision Making Scale [document on the Internet]. Ottawa: Ottawa Hospital Research Institute; © 1995 [modified 2010; cited 2015 09 25]. 3p. Available from http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_PrepDM.pdf

Your Opinions/*Knowledge*

Directions: **The following statements refer to general information about clinical trials. Please check the box next to each statement under your answer: agree, disagree, or unsure.**

	Agree	Disagree	Unsure
1. "Informed consent" means that I am given information about the trial so I can freely decide whether to participate.	❍*	❍	❍
2. "Standard treatments" are the best treatments currently known for a cancer.	❍*	❍	❍
3. Standard treatments are never as good as new research treatments.	❍	❍*	❍
4. Treatments used in clinical trials may cause side effects.	❍*	❍	❍
5. It is up to me to decide whether to be in a clinical trial.	❍*	❍	❍
6. Patients in clinical trials must get their care at different places from patients getting standard treatments.	❍	❍*	❍
7. If I were to join a clinical trial, I could decide to stop at any time.	❍*	❍	❍
8. "Randomization" means that my treatment will be chosen by chance.	❍*	❍	❍
9. Once I join a clinical trial, my own doctor will not know what happens to me.	❍	❍*	❍
10. Most clinical trials involve a placebo (sugar pill).	❍	❍*	❍
11. Side effects in clinical trials are usually worse than with standard treatments	❍	❍*	❍
12. Clinical trials are only used as a last resort.	❍	❍*	❍
13. The only way to find out about clinical trials is from my doctor.	❍	❍*	❍
14. Clinical trials are not appropriate for patients with cancer.	❍	❍*	❍
15. My doctor can start a clinical trial without the approval of professionals who	❍	❍*	❍

	Agree	Disagree	Unsure
protect patient rights.			
16. A clinical trial is available for anyone with cancer who wants to take part.	❍	❍*	❍
17. Institutional Review Boards review and monitor clinical trials to keep patients safe.	❍*	❍	❍
18. Informed Consent mainly protects researchers from lawsuits.	❍	❍*	❍
19. Clinical trials are done to improve standard treatments.	❍*	❍	❍

***** *Indicates the correct answer*
The correct answer received a score of 1; Incorrect answers and "Unsure" received a score of 0.

Your Opinions/*Attitudinal Barriers(6,7)*

Directions: **The following section contains items about your feelings regarding cancer and clinical trials. Please answer according to the following scale: Strongly Disagree, Somewhat Disagree, Neither Agree nor Disagree, Somewhat Agree, or Strongly Agree.**

	Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Strongly Agree
1. I think clinical trials are best used for people with cancer that can't be treated any other way.	❍	❍	❍	❍	❍
2. I think that being on a clinical trial is dangerous.	❍	❍	❍	❍	❍
3. I don't know where to find a clinical trial for me.	❍	❍	❍	❍	❍
4. I'm afraid that my health insurance won't pay for a clinical trial.	❍	❍	❍	❍	❍
5. I'm afraid of the side effects I'll have on a clinical trial.	❍	❍	❍	❍	❍
6. I wouldn't be willing to travel extra distance to take part in a clinical trial.	❍	❍	❍	❍	❍
7. I don't know what clinical trials are.	❍	❍	❍	❍	❍
8. I'm afraid that if I take part in a clinical trial my treatment will be selected at random by a computer rather than by my doctor.	❍	❍	❍	❍	❍

	Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Strongly Agree
9. I'm afraid I'll get a sugar pill (placebo) instead of real medicine on a clinical trial.	❍	❍	❍	❍	❍
10. I don't trust the medical system.	❍	❍	❍	❍	❍
11. I'm afraid that taking part in a clinical trial would make me sicker than I am now.	❍	❍	❍	❍	❍
12. I'm worried that my medical care won't be as good if I join a clinical trial.	❍	❍	❍	❍	❍
13. I'm worried I'd be treated like a number, not a person, on a clinical trial.	❍	❍	❍	❍	❍
14. I'm afraid I'll be used as a guinea pig if I'm in a clinical trial.	❍	❍	❍	❍	❍
15. It would be too upsetting for me to be on a clinical trial.	❍	❍	❍	❍	❍
16. I wouldn't be able to find transportation to get me to my clinical trial treatment center.	❍	❍	❍	❍	❍
17. I wouldn't be able to keep up with the clinical trial treatment schedule.	❍	❍	❍	❍	❍

	Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Strongly Agree
18. I'm too upset now to think about taking part in a clinical trial.	❍	❍	❍	❍	❍
19. I don't have time to take part in a clinical trial.	❍	❍	❍	❍	❍
20. I'm worried that I wouldn't be able to afford the costs of treatment on a clinical trial.	❍	❍	❍	❍	❍
21. I don't trust drug companies.	❍	❍	❍	❍	❍
22. I don't trust doctors.	❍	❍	❍	❍	❍
23. I wouldn't ask about clinical trials unless my doctor brought them up first.	❍	❍	❍	❍	❍
24. I'm worried that my family wouldn't want me to go on a clinical trial.	❍	❍	❍	❍	❍
25. I'm worried that going on a clinical trial would burden my family.	❍	❍	❍	❍	❍
26. I'm concerned that people other than my doctor would see my personal information if I was on a clinical trial.	❍	❍	❍	❍	❍

	Strongly Disagree	Somewhat Disagree	Neither Agree nor Disagree	Somewhat Agree	Strongly Agree
27. I'm worried that the treatment I'd receive on a clinical trial wouldn't work for me.	❍	❍	❍	❍	❍
28. I don't like to try new treatments until they've been around for a while.	❍	❍	❍	❍	❍

Scored from Strongly Disagree=1 to Strongly Agree=5. The higher the score, the stronger the barrier.

Your Feelings/*Cancer-Related Distress Impact of Events(53)***

See: Horowitz M, Wilner N, Alvarez W: Impact of Event Scale: a measure of subjective stress. Psychosom Med 41:209-18, 1979

Your Preferences/*Quality/Length of Life Preferences(38)***

Directions: Please answer each of the following questions by clicking the circle next to the answer you want to choose. Quality of life means how well a person generally feels, physically and emotionally, while dealing with their cancer, while length of life refers specifically to how long a person lives.

1. In light of your cancer diagnosis, how important is the quality of your life to you?
- ❍ **Not at all important**
- ❍ **Somewhat important**
- ❍ **Moderately important**
- ❍ **Quite a bit important**
- ❍ **Extremely important**

2. In light of your cancer diagnosis, how important is the remaining length of your life to you?
- ❍ **Not at all important**
- ❍ **Somewhat important**
- ❍ **Moderately important**
- ❍ **Quite a bit important**
- ❍ **Extremely important**

3. Please indicate which of these is most important to you by checking one of the following options:
- ❍ **Quality of life is all that matters.**
- ❍ **Quality of life is more important, but length of life also matters.**
- ❍ **Length of life is more important, but quality of life also matters.**
- ❍ **Length of life is all that matters.**

***** From Meropol NJ, Egleston BL, Buzaglo JS, et al: Cancer patient preferences for quality and length of life. Cancer 113:3459-66, 2008.

Your Preferences/*Control Preferences(41)*

See: Degner LF, Sloan JA, Venkatesh P: The Control Preferences Scale. Can J Nurs Res 29:21-43, 1997

Your Feelings/*Ottawa Self-Efficacy(54)***

<u>Directions</u>: Below are listed some things involved in making an informed choice about taking part in a clinical trial. Please show how confident you feel in doing these things by clicking the circle under the numbers from 0 (not at all confident) to 4 (very confident) for each item listed below.

I feel confident that I can:	not at all confident	0	1	2	3	4	very confident
1. Get the facts about clinical trials that are available to me.		❍	❍	❍	❍	❍	
2. Get the facts about the benefits of taking part in a clinical trial.		❍	❍	❍	❍	❍	
3. Get the facts about the risks and side effects of taking part in a clinical trial.		❍	❍	❍	❍	❍	
4. Understand the information enough to be able to make a choice about taking part in a clinical trial.		❍	❍	❍	❍	❍	
5. Ask questions without feeling dumb.		❍	❍	❍	❍	❍	
6. Express my concerns about taking part in a clinical trial.		❍	❍	❍	❍	❍	
7. Ask for advice.		❍	❍	❍	❍	❍	
8. Figure out the treatment choice that best suits me.		❍	❍	❍	❍	❍	
9. Handle unwanted pressure from others in making my choice about taking part in a clinical trial.		❍	❍	❍	❍	❍	
10. Let the medical team know what's best for me.		❍	❍	❍	❍	❍	
11. Delay my decision about taking part in a clinical trial if I feel I need more time.		❍	❍	❍	❍	❍	

Coding: Item score +1 = score (0=1, 1=2, 2=3, 4=5). Self-efficacy score = mean of items-1 multiplied by 25. The higher the score, the greater the self-efficacy.

*****Adapted from O'Connor AM. User Manual – Decision Self-Efficacy Scale [document on the Internet]. Ottawa: Ottawa Hospital Research Institute © 1995 [modified 2002; cited 2015 09 25]. 4 p. Available from http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decision_SelfEfficacy.pdf

Appendix 2: PRE-ACT Post-Intervention Assessment

Satisfaction with Information Received

<u>Directions:</u> The following questions ask about the information you received about clinical trials for treating cancer.

1. How satisfied are you with the <u>amount of information</u> you received?

- ❍ **Not at all satisfied**
- ❍ **A little satisfied**
- ❍ **Moderately satisfied**
- ❍ **Very satisfied**
- ❍ **Extremely satisfied**

2. How satisfied are you with the <u>way the information was presented to you</u>?

- ❍ **Not at all satisfied**
- ❍ **A little satisfied**
- ❍ **Moderately satisfied**
- ❍ **Very satisfied**
- ❍ **Extremely satisfied**

3. How satisfied are you with information you received about the <u>benefits</u> of clinical trials?

- ❍ **Not at all satisfied**
- ❍ **A little satisfied**
- ❍ **Moderately satisfied**
- ❍ **Very satisfied**
- ❍ **Extremely satisfied**

4. How satisfied are you with information you received about the <u>risks</u> of clinical trials?

- ❍ **Not at all satisfied**
- ❍ **A little satisfied**
- ❍ **Moderately satisfied**
- ❍ **Very satisfied**
- ❍ **Extremely satisfied**

Patient Evaluation of Intervention

Directions: **We would like to know what you think about the educational material you have just reviewed.**

1. Did this program help you feel more prepared to consider clinical trials as a way to treat your cancer?

- ❍ **Not at all**
- ❍ **Very little**
- ❍ **Somewhat**
- ❍ **Quite a bit**
- ❍ **A great deal**

2. Which of the following best describes your feelings about the length of this program?

- ❍ **Reasonable**
- ❍ **A little long**
- ❍ **Much too long**

3. The amount of information was:

- ❍ **Too much information**
- ❍ **Too little information**
- ❍ **Just right**

4. I found the presentation:

- ❍ **Slanted towards taking part in a clinical trial**
- ❍ **Slanted towards not taking part in a clinical trial**
- ❍ **Balanced**

5. Did you find this program useful for making your decision about treatment for cancer?

- ❍ **Yes**
- ❍ **No**

COMMENTS:

6. Do you think we included enough information to help a patient prepare to make a decision about taking part in a clinical trial?

- ❍ **Yes**
- ❍ **No**

COMMENTS:

7. What did you like about the program?

8. What suggestions do you have to improve the program?

Appendix 3: PRE-ACT Patient Post-Consultation Assessment

Consultation Content

Directions: We are interested in learning more about what you and your doctor and his/her team talked about during your appointment. Please answer the following questions regarding your visit.

1. Were clinical trials (therapy that is part of a research study) discussed during the consultation with your doctor?
- ❍ **Yes**
- ❍ **No**

2. Were specific clinical trials/protocols discussed to treat your cancer?
- ❍ **Yes**
- ❍ **No**

3. Were you offered a clinical trial as a treatment option?
- ❍ **Yes**
- ❍ **No**

If yes, please answer question 4. If no, skip to question 6.

4. Did you agree to take part in a clinical trial?
- ❍ **Yes**
- ❍ **No**

5. If no, why not? _____

6. Was standard therapy (cancer treatment not part of a research study / clinical trial) discussed as a treatment option?
- ❍ **Yes**
- ❍ **No**

7. Were you offered standard therapy as a treatment option?
- ❍ **Yes**
- ❍ **No**

8. Was supportive/palliative care alone (treatment of symptoms such as pain, nausea, fatigue) discussed as a treatment option?
- ❍ **Yes**
- ❍ **No**

9. Were you offered supportive/palliative care as a treatment option?
- ❍ **Yes**
- ❍ **No**

Satisfaction with Discussion about Clinical Trials

Directions: **We are interested in learning about how satisfied you were with your consultation with your doctor and his/her medical team. Please answer the following question regarding clinical trials.**

1. How satisfied are you with the amount of discussion about clinical trials that took place during your consultation with your doctor? Even if this topic was not discussed, you may still be satisfied or not satisfied.

- ❍ **Not at all satisfied**
- ❍ **A little satisfied**
- ❍ **Moderately satisfied**
- ❍ **Very satisfied**
- ❍ **Extremely satisfied**

Treatment Selection

Directions: **Please answer the following questions regarding treatment options discussed during your first consultation with the medical oncologist:**

1. Have you made a decision about the type of treatment that you would like to receive?

- ❍ **Yes**
- ❍ **No**

If you checked Yes to question 1 above, what treatment have you chosen?

- ❍ **Standard therapy (cancer treatment not part of a clinical trial / research study)**
- ❍ **Clinical trial / research study**
- ❍ **No treatment**
- ❍ **Supportive/palliative care alone (treatment of symptoms such as pain, nausea, fatigue)**
- ❍ **Other (please specify): _____**

2. If you chose to participate in a clinical trial / research study, how satisfied are you with the information you received about the study?

- ❍ **Not at all satisfied**
- ❍ **A little satisfied**
- ❍ **Moderately satisfied**
- ❍ **Very satisfied**
- ❍ **Extremely satisfied**

Your Treatment Decision/*Ottawa Decisional Conflict Scale(35)**

***** See: O'Connor AM. User Manual – Decisional Conflict Scale (16 items statement format) [document on the Internet]. Ottawa: Ottawa Hospital Research Institute; ©1993 [updated 2010; cited 2015 09 25]. 16 p. Available from http://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decisional_Conflict.pdf.

Have you decided to participate in a cancer clinical trial?

- ❍ **Yes**
- ❍ **No**

Appendix 4: List of Video Library Titles

Core Videos
What are clinical trials?
What is informed consent?
What is an IRB?
Tailored Videos
What is a placebo?
Will I have side effects on a clinical trial?
What is standard treatment?
Will I have to receive my care at a different clinic if I am on a clinical trial?
Is there a clinical trial for everyone?
Where can I find information about clinical trials?
Will my own doctor know what happens to me when I am on a clinical trial?
Will taking part in a clinical trial help me?
Who pays for the cost of a clinical trial?
Should I ask my doctor about clinical trials?
Are clinical trials only used as a last resort?
Are there ways to deal with transportation and financial issues?
What is randomization?
Is it safe to try new treatments that haven't been around for long?
What will pharmaceutical or drug companies gain from a clinical trial?
Can I trust the medical establishment?
How would clinical trials affect my family?
Will I get good care if I take part in a clinical trial?
How long do I need to stay in a clinical trial?
Are clinical trials appropriate for cancer patients?
How is my privacy protected on a clinical trial?
Will a clinical trial take up a lot of my time?
Will I be able to handle being in a clinical trial?
What will my doctor gain from this clinical trial research?
Is taking part in a clinical trial voluntary?

Appendix 5: Control Condition Adapted from NCI Text *

Introduction

Before you meet with your doctor, you may want to learn about different treatment options, including clinical trials. The following section of the PRE-ACT study contains information about clinical trials that may be of interest to you.

Introduction

If you have cancer, you may want to think about taking part in a clinical trial. Clinical trials are a treatment option for many people with cancer. This book explains cancer treatment clinical trials and gives you some things to think about when deciding whether to take part.

What Are Clinical Trials?

Clinical trials are research studies that involve people. They are the [mal step in a long process that begins with research in a lab and animal testing. Many treatments used today are the result of past clinical trials. In cancer research, clinical trials are designed to answer questions about new ways to:

- Treat cancer
- Find and diagnose cancer
- Prevent cancer
- Manage symptoms of cancer or its treatment

This booklet will focus on cancer treatment studies. These studies are designed to answer questions about new treatments or new ways of using an old treatment and how well they work. These trials test many types of treatments, such as new:

- Drugs or vaccines
- Ways to do surgery or give radiation therapy
- Combinations of treatments

Many treatments used today are the results of past clinical trials.

Clinical Trials Take Place in Phases

For a treatment to become part of standard treatment, it must first go through 3 or 4 clinical trial phases. You do not have to take part in all phases. The early phases make sure the treatment is safe. Later phases show if it works better than the standard treatment.

Purpose	**Number of people who take part**
Phase I	15-30 people
To find a safe dose	
To decide how the new treatment should be given	
To see how the new treatment affects the human body	
Phase II	Less than 100 people
To determine if the new treatment has an effect on a certain cancer	
To see how the new treatment affects the human body	
Phase III	From 100 to thousands of people

To compare the new treatment (or new use of a treatment) with the current standard treatment	
Phase IV	Several hundred to several thousand people
To further assess the long-term safety and effectiveness of a new treatment	

Clinical Trials Follow Strict Guidelines

The guidelines that clinical trials follow clearly state who will be able to join the study and the treatment plan. Every trial has a person in charge, usually a doctor, who is called the principal investigator. The principal investigator prepares a plan for the study, called a protocol, which is like a recipe for conducting a clinical trial. The protocol explains what the trial will do, how the study will be carried out, and why each part of the study is necessary. It includes information on:

- The reason for doing the study
- Who can join the study
- How many people are needed for the study
- Any drugs they will take, the dose, and how often
- What medical tests they will have and how often
- What information will be gathered about them

Who Can Join a Clinical Trial?

Based on the questions the research is trying to answer, each clinical trial protocol clearly states who can or cannot join the trial.

Common criteria for entering a trial:

- Having a certain type or stage of cancer
- Having received a certain kind of therapy in the past
- Being in a certain age group

Criteria such as these help ensure that people in the trial are as alike as possible. This way doctors can be sure that the results are due to the treatment being studied and not other factors.

These criteria also help ensure:

- **Safety**
  Some people have health problems besides cancer that could be made worse by the treatments in a study. If you are interested in joining a trial, you will receive medical tests to be sure that you are not put at increased risk.
- **Accurate and meaningful study results**
  You may not be able to join some clinical trials if you already have had another kind of treatment for your cancer. Otherwise, doctors could not be sure whether your results were due to the treatment being studied or the earlier treatment.

Randomization

Randomization is a process used in some clinical trials to prevent bias. Bias occurs when a trial's results are affected by human choices or other factors not related to the treatments being tested. Randomization helps ensure that unknown factors do not affect trial results.

In a randomized clinical trial, you will be assigned by chance to either a control group or

an investigational group.
Randomization is used in all phase III and some phase II trials. These trials are called randomized clinical trials. If you participate in such a trial, you will be assigned by chance to either an investigational group or a control group. Your assignment will be determined with a computer program or table of random numbers.

- If you are assigned to the control group, you will get the most widely accepted treatment (standard treatment) for your cancer.
- If you are assigned to the investigational group, you will get the new treatment being tested.

Comparing these groups to each other often clearly shows which treatment is more effective or has fewer side effects. If you are thinking about joining a randomized clinical trial, you need to understand that you have an equal chance to be assigned to either one of the groups. The doctor does not choose the group for you.

Will I get a placebo?

A placebo is designed to look like the medicine being tested, but it is not active. Placebos are almost never used in cancer treatment trials. In some cases, a study may compare standard treatment plus a new treatment, to standard treatment plus a placebo. You will be told if the study uses a placebo.

Patient Protection

Federal rules help ensure that clinical trials are run in an ethical manner.
Your rights and safety are protected through:

- Informed consent
- Careful review and approval of the clinical trial protocol by two review panels. These panels include:
    - A scientific review panel
    - An institutional review board (IRB)
- Ongoing monitoring provided during the trial by:
    - The IRB
    - Data and Safety Monitoring Boards (DSMBs) for phase III
    - trials
    - Your research team

Informed Consent

Informed consent is a process through which you learn the purpose, risks, and benefits of a clinical trial before deciding whether to join. It is a critical part of ensuring patient safety in research. During the informed consent process you learn important information about a clinical trial. This information can help you decide whether to join. During the informed consent process, you learn important information about the clinical trial that can help you decide whether to take part.

The research team, which is made up of doctors and nurses, first explains the trial to you. The team explains the trial's:

- Purpose

- Procedures
- Risks and benefits

They will also discuss your rights, including your right to:

- Make a decision about participating
- Leave the study at any time

If you decide to leave the study, your doctor will discuss other treatment options with you. Before agreeing to take part in a trial, you have the right to:

- Learn about all your treatment options
- Learn all that is involved in the trial - including all details about treatment, tests, and possible risks and benefits
- Discuss the trial with the principal investigator and other members of the research team
- Both hear and read the information in language you can understand

After discussing all aspects of the study with you, the team gives you an informed consent form to read. The form includes written details about the information that was discussed and also describes the privacy of your records. If you agree to take part in the study, you sign the form. But even after you sign the consent form, you can leave the study at any time. Most clinical trials have to go through different types of review that are designed to protect all people who take part. These reviews are conducted by scientific review panels, Institutional Review Boards (IRBs), and Data and Safety Monitoring Boards (DSMBs).

Scientific Review Panels

This panel is made up of experts who review a clinical trial protocol before it starts accepting patients to make sure it is based on sound science. All clinical trials that are funded by the Government must go through this review. Many other clinical trial sponsors, such as drug companies, also seek expert advice on the scientific merit of their trial protocols.

Institutional Review Boards

This board also reviews a clinical trial protocol before it starts accepting patients. The board members make sure the risks involved in the trial are reasonable when compared to the possible benefits. They also closely watch the ongoing progress of the trial from beginning to end. Federal rules require that each IRB be made up of at least 5 people. One member must be from outside the institution running the trial. IRBs are usually made up of a mix of medical specialists and members of the community. Many include members from diverse careers and backgrounds. In most cases IRBs are located where the trial is to take place. Many institutions that carry out clinical trials have their own IRBs.

Data and Safety Monitoring Boards (DSMBs)

For phase III trials, DSMBs monitor the trial to help ensure your safety. They may also be appropriate and necessary for certain phase I and II clinical trials. A DSMB is an independent committee made up of statisticians, physicians, and other experts.

The Board must:

• Ensure that any risks that come from being in the study are reduced as much as possible
• Ensure that the data are sound
• Stop a trial if safety concerns come up or as soon as its objectives have been met

Deciding to Take Part in Clinical Trials

Whenever you need treatment for your cancer, clinical trials may be an option for you. Choosing to join a clinical trial is something only you, those close to you, and your doctors and nurses can decide together. This section has information you can use when thinking about your treatment choices and making your decision.

Weighing the Pros and Cons

As a treatment option, a clinical trial has possible benefits as well as drawbacks. You may want to discuss the following issues with your doctor and the people close to you.

Possible Benefits

- Clinical trials offer high-quality cancer care. If you are in a randomized study and do not receive the new treatment being tested, you will receive the best known standard treatment. This may be as good as, or better than, the new approach.
- If a new treatment is proven to work and you are taking it, you may be among the first to benefit.
- By looking at the pros and cons of clinical trials and your other treatment choices, you are taking an active role in a decision that affects your life.
- You have the chance to help others and improve cancer treatment.

Possible Drawbacks

- New treatments under study are not always better than, or even as good as, standard care.
- If you receive standard care instead of the new treatment being tested, it may not be as effective as the new approach.
- New treatments may have side effects that doctors do not expect or that are worse than those of standard treatment.
- Even if a new treatment has benefits, it may not work for you. Even standard treatments, proven effective for many people, do not help everyone.
- Health insurance and managed care providers do not always cover all patient care costs in a study. What they cover varies by plan and by study. To find out in advance what costs are likely to be paid in your case, check with your insurance company and talk to a doctor, nurse or social worker from the study. If a new treatment is proven to work and you are taking it, you may be among the first to benefit.

Questions to Ask

If you are thinking about taking part in a clinical trial, here are some questions that can help you decide.

About this trial

- Why is this trial being done?
- Why do the doctors who designed the trial believe that the treatment being studied may be better than the one being used now?
- Why may it not be better?
- How long will I be in the trial?

- What kinds of tests and treatments are involved?
- What are the possible side effects or risks of the new treatment?
- What are the possible benefits?
- How will the doctor know if the treatment is working?

Costs
- Will I have to pay for any of the treatments or tests?
- What costs will my health insurance cover?

Daily life
- How could the trial affect my daily life?
- How often will I have to come to the hospital or clinic?
- Will I have to travel long distances?

Comparing choices
- What are my other treatment choices, including standard treatments?
- How does the treatment I would receive in this trial compare with the other treatment choices?

How to Find Clinical Trials

The National Cancer Institute, drug companies, medical institutions, and other organizations sponsor clinical trials. Clinical trials take place in many settings, such as cancer centers, large medical centers, small hospitals, and doctors' offices.

The National Cancer Institute maintains the most complete database of cancer clinical trials in the country. This database is called PDQ®. The following resources from the National Cancer Institute can help you search PDQ® and see if there is a trial for your type and stage of cancer.
National Cancer Institute
Cancer Information Service
Toll-free: 1-800-4-CANCER (1-800-422-6237)
TTY: 1-800-332-8615

Answers questions about cancer clinical trials and cancer-related services and helps users find information on the NCI Web site. Provides NCI printed materials.
Online: http://www.cancer.gov/clinicaltrials
Chat online: www.cancer.gov/help

Before you see your Doctor ...

Now that you've gotten some information about clinical trials, we'd like to ask you a few more questions before you see your doctor. This should only take about 15 minutes of your time. Please answer each question to the best of your ability. Feel free to contact the study staff if you have any questions.
* Adapted from the NCI website (Current version of NCI text: http://www.cancer.gov/clinicaltrials/learningabout)

Appendix 6. Comparisons of demographic characteristics of patients who dropped out vs. completed visits, and effects of dropout on balance in baseline characteristics, PRE-ACT vs. Control

Table 1. Comparisons of demographic characteristics of subjects who dropped out vs. did not drop out between baseline and post-intervention assessment (study arms pooled).

	Dropout	Completer	p-value[†]
	N=145	N=1090	
Age (mean ± SD)	59.8 ± 12.4	57.7 ± 11.7	0.0396[*]
Gender N (%)			
Female	83 (57.24)	639 (58.62)	0.7510
Male	62 (42.76)	451 (41.38)	
Race N (%)			
White (Non-Hispanic)	121 (85.82)	945 (86.70)	0.7725
Non-White	20 (14.18)	145 (13.30)	
Education N (%)			
High school graduate or less	40 (27.59)	251 (23.05)	0.2266
Some college or college graduate	105 (72.41)	838 (76.95)	
Marital Status N (%)			
Married/Domestic Partner	93 (64.58)	823 (75.50)	0.0049
Other	51 (35.42)	267 (24.50)	
Employment N (%)			
Employed	53 (37.06)	500 (45.91)	0.1234
Unemployed	39 (27.27)	242 (22.22)	
Retired	51 (35.66)	347 (31.86)	
Metastatic Status N (%)			
Metastatic	69 (53.91)	454 (44.95)	0.0554
Non-metastatic	59 (46.09)	556 (55.05)	

[†] p-value from Chi-squared test
[*] p-value from T-test

Table 2. Comparisons of demographic characteristics of subjects who dropped out vs. did not drop out between baseline and post-intervention assessment, by study arm.[1]

	Control			PRE-ACT		
	Dropout	Completer	p-value[2]	Dropout	Completer	p-value[2]
	N=40	N=581		N=105	N=509	
Age (mean ± SD)	60.7 ± 12.8	58.1 ± 11.7	0.1699[3]	59.5 ± 12.4	57.2 ± 11.7	0.0733[3]
Gender N (%)						
Female	24 (60.00)	339 (58.35)	0.8375	59 (56.19)	300 (58.94)	0.6028
Male	16 (40.00)	242 (41.65)		46 (43.81)	209 (41.06)	
Race N (%)						
White(Non-Hispanic)	30 (78.95)	498 (85.71)	0.2538	91 (88.35)	447 (87.82)	0.8803
Non-White	8 (21.05)	83 (14.29)		12 (11.65)	62 (12.18)	
Education N (%)						
High school graduate or less	14 (35.00)	134 (23.06)	0.0866	26 (24.76)	117 (23.03)	0.7027
Some college or college graduate	26 (65.00)	447 (76.94)		79 (75.24)	391 (76.97)	
Marital Status N (%)						
Married/Domestic Partner	25 (62.50)	437 (75.22)	0.0747	68 (65.38)	386 (75.83)	0.0267
Other	15 (37.50)	144 (24.78)		36 (34.62)	123 (24.17)	
Employment N (%)						
Employed	14 (36.84)	268 (46.21)	0.3887	39 (37.14)	232 (45.58)	0.1899
Unemployed	8 (21.05)	128 (22.07)		31 (29.52)	114 (22.40)	
Retired	16 (42.11)	184 (31.72)		35 (33.33)	163 (32.02)	
Metastatic Status N (%)						
Metastatic	21 (58.33)	253 (46.68)	0.1751	48 (52.17)	201 (42.95)	0.1036
Non-metastatic	15 (41.67)	289 (53.32)		44 (47.83)	267 (57.05)	

[1] Comparisons of characteristics of PRE-ACT vs. Control patients, made among completers and among dropouts, found no statistically significant differences (all p-values >0.05).
[2] p-value from Chi-squared test
[3] p-value from T-test

Table 3. Comparisons of demographic characteristics of subjects who dropped out vs. did not drop out between baseline and post-consultation assessment (study arms pooled).

	Dropout	Completer	p-value[†]
	N=500	N=735	
Age (mean ± SD)	58.2 ± 11. 8	57.7 ± 11.79	0.4912[*]
Gender N (%)			
Female	290 (58.00)	432 (58.78)	0.7860
Male	210 (42.00)	303 (41.22)	
Race N (%)			
White (Non-Hispanic)	426 (85.89)	640 (87.07)	0.5485
Non-White	70 (14.11)	95 (12.93)	
Education N (%)			
High school graduate or less	135 (27.00)	156 (21.25)	0.0196
Some college or college graduate	365 (73.00)	578 (78.75)	
Marital Status N (%)			
Married/Domestic Partner	355 (71.14)	561 (76.33)	0.0410
Other	144 (28.86)	174 (23.67)	
Employment N (%)			
Employed	217 (43.66)	336 (45.71)	0.2719
Unemployed	125 (25.15)	156 (21.22)	
Retired	155 (31.19)	243 (33.06)	
Metastatic Status N (%)			
Metastatic	239 (53.47)	284 (41.10)	<.0001
Non-metastatic	208 (46.53)	407 (58.90)	

[†] p-value from Chi-squared test
[*] p-value from T-test

Table 4. Comparisons of demographic characteristics of subjects who dropped out vs. did not drop out between baseline and post-consultation assessment, by study arm.[1]

	Control			PRE-ACT		
	Dropout	Completer	p-value[2]	Dropout	Completer	p-value[2]
	N=244	N=377		N=256	N=358	
Age (mean ± SD)	57.8 ± 11.5	58.5 ± 11.9	0.4761[3]	58.5 ± 12.0	56.9 ± 11.6	0.0873[3]
Gender N (%)						
Female	145 (59.43)	218 (57.82)	0.6925	145 (56.64)	214 (59.78)	0.4369
Male	99 (40.57)	159 (42.18)		111 (43.36)	144 (40.22)	
Race N (%)						
White(Non-Hispanic)	203 (83.88)	325 (86.21)	0.4259	223 (87.80)	315 (87.99)	0.9423
Non-White	39 (16.12)	52 (13.79)		31 (12.20)	43 (12.01)	
Education N (%)						
High school graduate or less	66 (27.05)	82 (21.75)	0.1301	69 (26.95)	74 (20.73)	0.0723
Some college or college graduate	178 (72.95)	295 (78.25)		187 (73.05)	283 (79.27)	
Marital Status N (%)						
Married/Domestic Partner	179 (73.36)	283 (75.07)	0.6343	176 (69.02)	278 (77.65)	0.0162
Other	65 (26.64)	94 (24.93)		79 (30.98)	80 (22.35)	
Employment N (%)						
Employed	106 (43.98)	176 (46.68)	0.1314	111 (43.36)	160 (44.69)	0.9362
Unemployed	63 (26.14)	73 (19.36)		62 (24.22)	83 (23.18)	
Retired	72 (29.88)	128 (33.95)		83 (32.42)	115 (32.12)	
Metastatic Status N (%)						
Metastatic	125 (56.05)	149 (41.97)	0.0010	114 (50.89)	135 (40.18)	0.0124
Non-metastatic	98 (43.95)	206 (58.03)		110 (49.11)	201 (59.82)	

[1] Comparisons of characteristics of PRE-ACT vs. Control patients, made among completers and among dropouts, found no statistically significant differences (all p-values >0.05).
[2] p-value from Chi-squared test
[3] p-value from T-test

Table 5. Comparisons of demographic characteristics of subjects who dropped out vs. did not drop out between post-intervention and post-consultation assessments (study arms pooled).

	Dropout	Completer	p-value[†]
	N=355	N=735	
Age (mean ± SD)	57.5 ± 11.5	57.7 ± 11.8	0.8038[*]
Gender N (%)			
Female	207 (58.31)	432 (58.78)	0.8837
Male	148 (41.69)	303 (41.22)	
Race N (%)			
White (Non-Hispanic)	305 (85.92)	640 (87.07)	0.5974
Non-White	50 (14.08)	95 (12.93)	
Education N (%)			
High school graduate or less	95 (26.76)	156 (21.25)	0.0431
Some college or college graduate	260 (73.24)	578 (78.75)	
Marital Status N (%)			
Married/Domestic Partner	262 (73.80)	561 (76.33)	0.3639
Other	93 (26.20)	174 (23.67)	
Employment N (%)			
Employed	164 (46.33)	336 (45.71)	0.3589
Unemployed	86 (24.29)	156 (21.22)	
Retired	104 (29.38)	243 (33.06)	
Metastatic Status N (%)			
Metastatic	170 (53.29)	284 (41.10)	0.0003
Non-metastatic	149 (46.71)	407 (58.90)	

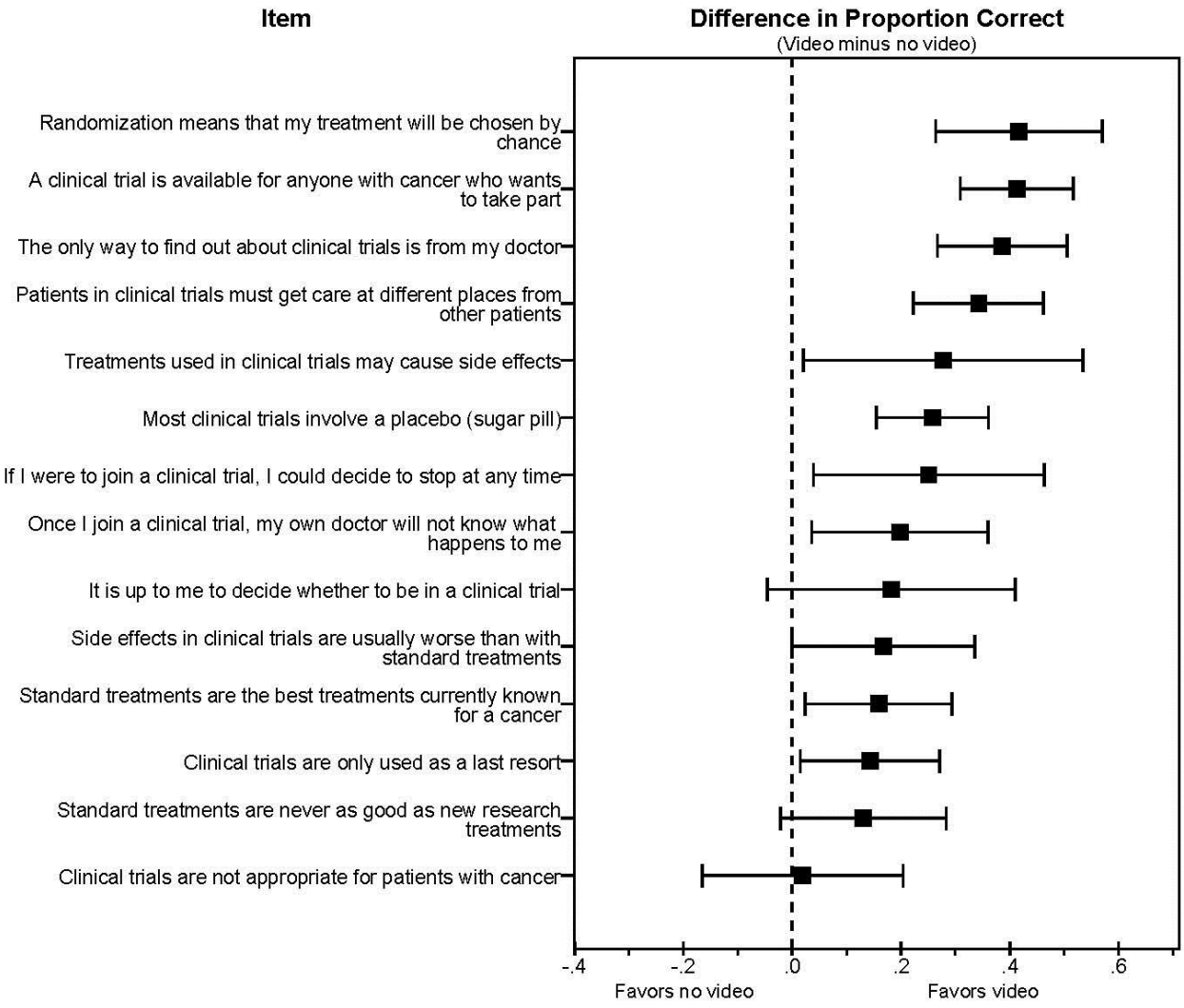
[†] p-value from Chi-squared test
[*] p-value from T-test

Table 6. Summary of Comparisons of Demographic Characteristics between Lost Subjects vs. Not Lost Subjects from Post-Intervention Assessment to Post-Consultation[1]

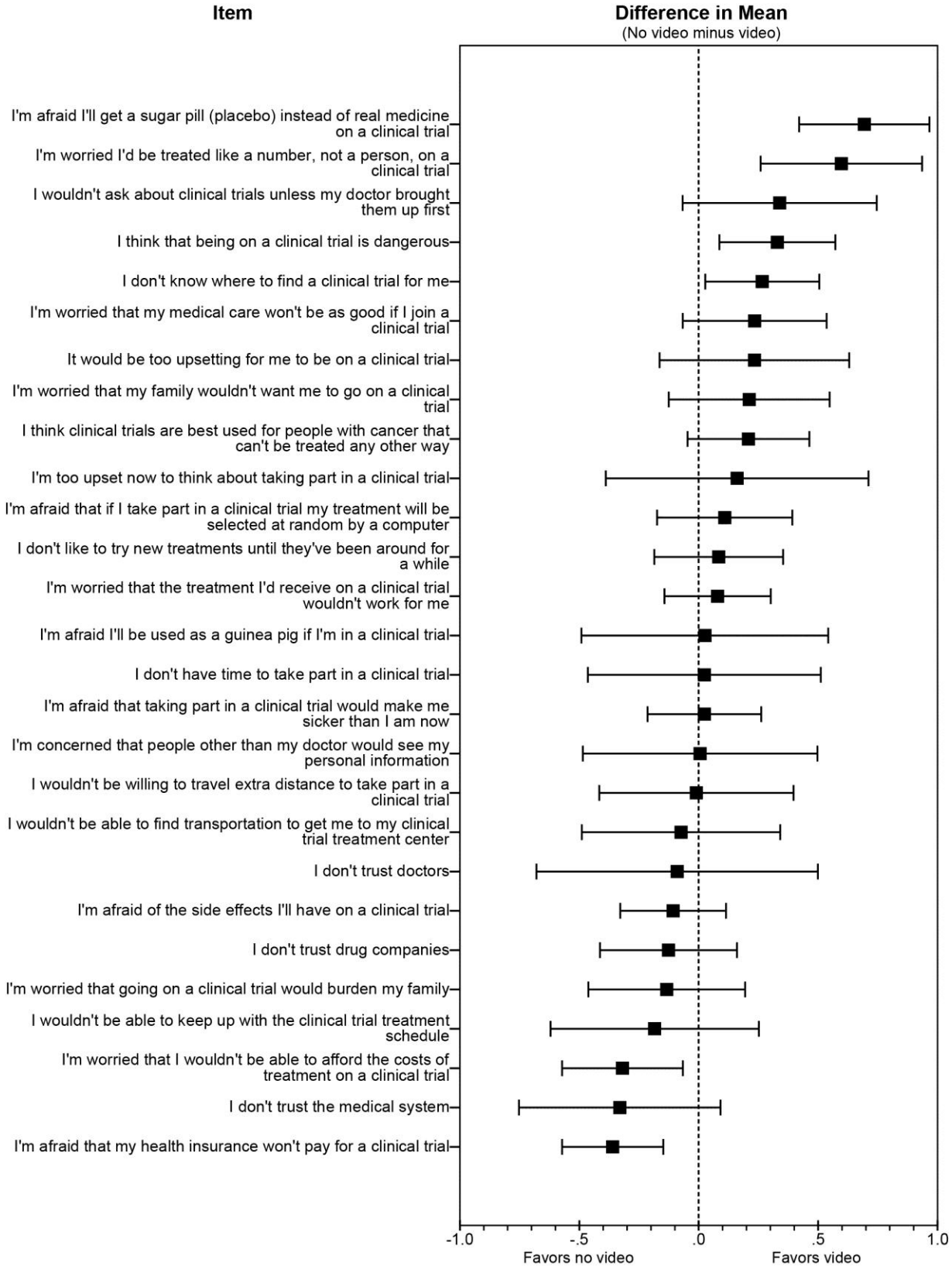
	Control			PRE-ACT		
	Dropout	Completer	p-value[2]	Dropout	Completer	p-value[2]
	N=204	N=377		N=151	N=358	
Age (mean ± SD)	57.3 ± 11.2	58.5 ± 11.9	0.2163[3]	57.9 ± 11.8	56.9 ± 11.6	0.3702[3]
Gender N (%)						
Female	121 (59.31)	218 (57.82)	0.7282	86 (56.95)	214 (59.78)	0.5543
Male	83 (40.69)	159 (42.18)		65 (43.05)	144 (40.22)	
Race N (%)						
White(Non-Hispanic)	173 (84.80)	325 (86.21)	0.6446	132 (87.42)	315 (87.99)	0.8571
Non-White	31 (15.20)	52 (13.79)		19 (12.58)	43 (12.01)	
Education N (%)						
High school graduate or less	52 (25.49)	82 (21.75)	0.3071	43 (28.48)	74 (20.73)	0.0580
Some college or college graduate	152 (74.51)	295 (78.25)		108 (71.52)	283 (79.27)	
Marital Status N (%)						
Married/Domestic Partner	154 (75.49)	283 (75.07)	0.9101	108 (71.52)	278 (77.65)	0.1400
Other	50 (24.51)	94 (24.93)		43 (28.48)	80 (22.35)	
Employment N (%)						
Employed	92 (45.32)	176 (46.68)	0.0702	72 (47.68)	160 (44.69)	0.7611
Unemployed	55 (27.09)	73 (19.36)		31 (20.53)	83 (23.18)	
Retired	56 (27.59)	128 (33.95)		48 (31.79)	115 (32.12)	
Metastatic Status N (%)						
Metastatic	104 (55.61)	149 (41.97)	0.0025	66 (50.00)	135 (40.18)	0.0534
Non-metastatic	83 (44.39)	206 (58.03)		66 (50.00)	201 (59.82)	

[1] Comparisons of characteristics of PRE-ACT vs. Control patients, made among completers and among dropouts, found no statistically significant differences (all p-values >0.05).
[2] p-value from Chi-squared test
[3] p-value from T-test

Appendix 7. Impact of Videos on Change in Knowledge Score



Appendix 8. Impact of Videos on Change in Attitudinal Barrier Scores



LEGENDS

Figure 1. PRE-ACT Theoretical Model

No legend

Table 1. Demographic and Clinical Characteristics

No legend

Figure 2. CONSORT diagram

No legend

Table 2. Knowledge and Attitudinal Barrier Survey Items

No legend

Table 3. Knowledge, Attitudes, and Preparation Scores, Control vs PRE-ACT

No legend

Figure 3. Demographic Influences on Treatment Effect

Means and 95% confidence intervals for Demographic influence on Treatment Effect. Means calculated are Post-Pre for PRE-ACT minus Post-Pre for Control, for Knowledge and Preparation. Means for Attitudinal Barriers are calculated as Post-Pre for Control minus Post-Pre for PRE-ACT, to allow same direction of differences for all scales.

Table 4. PRE-ACT Program Satisfaction, Control vs. PRE-ACT

No legend

Appendix 1. PRE-ACT BASELINE ASSESSMENT (What Participat Saw/*Scale Name*

No legend

Appendix 2. PRE-ACT Post-Intervention Assessment

The Post-Intervention Assessment consisted of the baseline assessment (without Demographics), plus the following scales asking them about their satisfaction with the intervention, as well as for feedback on the program.

Appendix 3. PRE-ACT Post-Consultation Assessment

No legend

Appendix 4. List of Video Library Titles

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Appendix 5. Control Condition Adapted from NCI Text

Adapted text from NCI (Current version of NCI text: http://www.cancer.gov/clinicaltrials/learningabout)

Appendix 6. Appendix 6: Appendix 6: Comparisons of demographic characteristics of patients who dropped out vs. completed visits, and effects of dropout on balance in baseline characteristics, PRE-ACT vs. Control

No legend

Appendix 7. Impact of Videos on Change in Knowledge Score

For subjects in the PRE-ACT arm who did not have a correct response to each knowledge item at baseline, the proportions answering the item correctly on the post-test were compared between those who watched the associated video vs. those who did not watch the assigned video. Positive differences in proportions indicate that those who watched the video had betters scores for the item on the post-test compared to those who did not watch the video.

Appendix 8. Impact of Videos on Change in Attitudinal Barrier Scores

For subjects in the PRE-ACT arm who answered 3=”Neither Agree nor Disagree “, 4=”Somewhat Agree “, or 5=”Strongly Agree“ to each attitudinal barrier item were divided into those who watched vs. did not watch the assigned video addressing that particular barrier, and the difference in mean post-test scores between those not watching vs. watching the video are summarized (mean and 95% CI). Mean differences that are positive indicate that those watching the video had more favorable post-test scores compared to those who did not watch the video.